IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

JANA SEDERHOLM, et al.,

Plaintiffs,

v. CIVIL ACTION NO. 2:13-cv-12510

BOSTON SCIENTIFIC CORPORATION,

Defendant.

MEMORANDUM OPINION AND ORDER
(*Daubert* Motions)

Pending before the court are several *Daubert* motions filed by both the defendant and the plaintiffs. Briefing is complete regarding these motions, and the motions are now ripe for consideration.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation ("MDL") concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 75,000 cases currently pending, approximately 19,000 of which are in the Boston Scientific Corporation ("BSC") MDL, MDL No. 2326. The parties have retained experts to render opinions regarding the elements of the case's various causes of action, and the instant motions involve the parties' efforts to exclude or limit the experts' opinions pursuant to *Daubert v. Merrell Dow Pharm.,*

Inc., 509 U.S. 579 (1993).

II. Legal Standard

Under Rule 702 of the Federal Rules of Evidence, expert testimony is admissible if the expert is "qualified . . . by knowledge, skill, experience, training, or education" and if his testimony is (1) helpful to the trier of fact in understanding the evidence or determining a fact in issue; (2) "based upon sufficient facts or data;" and (3) "the product of reliable principles and methods" that (4) have been reliably applied "to the facts of the case." Fed. R. Evid. 702. The Supreme Court has established a two-part test to govern the admissibility of expert testimony under Rule 702: the evidence is admitted if it "rests on a reliable foundation and is relevant." *Daubert*, 509 U.S. at 597. The proponent of expert testimony does not have the burden to "prove" anything to the court. *Md. Cas. Co. v. Therm-O-Disk, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). He or she must, however, "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Id.*

The district court is the gatekeeper. "[E]xpert witnesses have the potential to be both powerful and quite misleading," so the court must "ensure that any and all scientific testimony . . . is not only relevant, but reliable." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999); *Daubert*, 509 U.S. at 588, 595). In carrying out this role, I "need not determine that the proffered expert testimony is irrefutable or certainly correct"—"[a]s with all other admissible evidence, expert testimony is subject to testing by 'vigorous cross-examination, presentation of contrary evidence, and careful

instruction on the burden of proof.'" *United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006) (quoting *Daubert*, 509 U.S. at 596); *see also Md. Cas. Co.*, 137 F.3d at 783 (noting that "[a]ll *Daubert* demands is that the trial judge make a 'preliminary assessment' of whether the proffered testimony is both reliable . . . and helpful").

Daubert mentions specific factors to guide the court in making the overall reliability determinations that apply to expert evidence. These factors include (1) whether the particular scientific theory "can be (and has been) tested;" (2) whether the theory "has been subjected to peer review and publication;" (3) the "known or potential rate of error;" (4) the "existence and maintenance of standards controlling the technique's operation;" and (5) whether the technique has achieved "general acceptance" in the relevant scientific or expert community. *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593–94). Despite these factors, "[t]he inquiry to be undertaken by the district court is 'a flexible one' focusing on the 'principles and methodology' employed by the expert, not on the conclusions reached." *Westberry*, 178 F.3d at 261 (quoting *Daubert*, 509 U.S. at 594–95); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999) ("[T]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony." (citation omitted)); *Crisp*, 324 F.3d at 266 (noting "that testing of reliability should be flexible and that *Daubert*'s five factors neither necessarily nor exclusively apply to every expert").

With respect to relevance, the second part of the analysis, *Daubert* further

explains:

> Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful. The consideration has been aptly described by Judge Becker as one of fit. Fit is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes. . . . Rule 702's helpfulness standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

Daubert, 509 U.S. at 591–92 (citations and quotation marks omitted).

Ultimately, the district court has broad discretion in determining whether to admit or exclude expert testimony, and the "the trial judge must have considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable." *Cooper*, 259 F.3d at 200 (quoting *Kumho Tire*, 526 U.S. at 152).

III. Preliminary Matters

I begin by addressing a few preliminary matters that affect many of the *Daubert* motions. First, both parties consistently challenge experts' opinions as improper state-of-mind or legal-conclusion testimony. As I have maintained throughout these MDLs, I will not permit the use of experts to usurp the jury's fact-finding function by allowing an expert to testify as to a party's knowledge, state of mind, or whether a party acted reasonably. *See, e.g.*, *In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013) (excluding expert opinions on the defendant's knowledge, state of mind, alleged bad acts, failures to act, and corporate conduct and ethics). The reasonableness of conduct and a party's then-existing state of mind "are the sort of questions that lay jurors have been answering without expert assistance

from time immemorial," and therefore, these matters are not appropriate for expert testimony. *Kidder v. Peabody & Co. v. IAG Int'l Acceptance Grp., N.V.*, 14 F. Supp. 2d 391, 404 (S.D.N.Y. 1998); *see also In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 546 (S.D.N.Y. 2004) ("Inferences about the intent and motive of parties or others lie outside the bounds of expert testimony.").[1] Likewise, "opinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible." *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006). An expert may not state his opinion using "legal terms of art," such as "defective," "unreasonably dangerous," or "proximate cause." *See Perez v. Townsend Eng'g Co.*, 562 F. Supp. 2d 647, 652 (M.D. Pa. 2008).

I have diligently applied these rules to previous expert testimony, and I continue to apply them in this case. This does not mean that each objection to state-of-mind or legal-conclusion testimony raised in these motions is valid. But I will not parse the numerous reports and thousand-page depositions for each expert to determine the validity of these same objections. Instead, the onus is on counsel to tailor expert testimony at trial in accordance with the above directive. Therefore, unless otherwise necessary, the remainder of this opinion does not address objections brought against an expert based on improper state-of-mind or legal-conclusion testimony.

[1] On a related note, I caution the parties against introducing corporate evidence through expert witnesses. Although an expert may testify about his review of internal corporate documents solely for the purpose of explaining the basis for his or her opinions—assuming the opinions are otherwise admissible—he or she may not be offered solely as a conduit for corporate information. There is no reason why the plaintiffs require an expert to opine on such facts.

I also note that several of the *Daubert* motions concern expert opinions entirely unrelated to the individual plaintiffs at bar. For example, some experts have opined on general and specific causation with the specific causation portion of the opinion pertaining to wave plaintiffs other than the plaintiffs in this particular case. In addition, the parties filed a total of sixteen *Daubert* motions involving, in many instances, duplicative experts. In an effort to remedy this problem of blanketed, duplicative *Daubert* motions, I directed the parties to file disclosures, indicating who, out of the sixteen challenged experts, they plan to call at trial for each case. *See* Pretrial Order No. 121, at 5–6 [ECF No. 53]. Through these disclosures, I hoped to gain a better understanding of the particular arguments at issue, thereby refining my *Daubert* rulings for the benefit of the receiving judge. Rather than aiding the court in this endeavor, however, the parties effectively ignored the pretrial order, identifying *all sixteen* of the challenged experts as probable expert witnesses. *See* BSC's Disclosure Required by Pretrial Order No. 121 [ECF No. 55]; Pls.' Disclosure Required by Pretrial Order No. 121 [ECF No. 58]. Without guidance from the parties to the contrary, I have thus limited my review of the *Daubert* motions to only those arguments and opinions related to the instant plaintiffs. In other words, I disregard arguments included in the briefing directed exclusively at other wave plaintiffs and, consequently, irrelevant to *this* case.

Further, I am compelled to comment on the parties' misuse of my previous *Daubert* rulings on several of the experts offered in this case. *See generally Sanchez v. Bos. Sci. Corp.*, No. 2:12-cv-05762, 2014 WL 4851989 (S.D. W. Va. Sept. 29, 2014);

Tyree v. Bos. Sci. Corp., 54 F. Supp. 3d 501 (S.D. W. Va. 2014); *Eghnayem v. Bos. Sci. Corp.*, 57 F. Supp. 3d 658 (S.D. W. Va. 2014). The parties have, for the most part, structured their *Daubert* arguments as a response to these prior rulings, rather than an autonomous challenge to or defense of an expert's opinion based on its reliability and relevance. In other words, the parties have comparatively examined each expert's opinions and have largely overlooked *Daubert*'s core considerations for assessing expert testimony. Although I recognize the tendency of my prior evidentiary determinations to influence subsequent motions practice, counsels' expectations that I align with these previous rulings when faced with a different record are remiss, especially when an expert has issued new reports and given additional deposition testimony.

Mindful of my role as gatekeeper of expert testimony, as well as my duty to "respect[ ] the individuality" of each MDL case, *see In re Phenylpropanolamine Prods. Liab. Litig.*, 460 F.3d 1217, 1231 (9th Cir. 2006), I refuse to credit *Daubert* arguments that simply react to the court's rulings in *Sanchez* and its progeny. Indeed, I feel bound by these earlier cases only to the extent that the expert opinions and *Daubert* objections presented to the court then are identical to those presented now. Otherwise, I assess the parties' *Daubert* arguments anew. That is, in light of the particular opinions and objections currently before me, I assess "whether the reasoning or methodology underlying the testimony is scientifically valid" and "whether that reasoning or methodology properly can be applied to the facts in issue." *Daubert*, 509 U.S. at 592–93. Any departure from *Sanchez*, *Eghnayem*, or *Tyree* does

not constitute a "reversal" of these decisions and is instead the expected result of the parties' submission of updated expert reports and new objections to the opinions contained therein.

Finally, I have attempted to resolve all possible disputes before transfer or remand, including those related to the admissibility of expert testimony pursuant to *Daubert*. Nevertheless, in some instances I face *Daubert* challenges where my interest in accuracy counsels reserving ruling until the reliability of an expert's testimonial opinion may be evaluated at trial. At trial, the opinions will be tested by precise questions asked and answered. The alternative of live *Daubert* hearings is impossible before transfer or remand because of the numerosity of such motions in these seven related MDLs. As these MDLs have grown and the expert testimony has multiplied, I have become convinced that the critical gatekeeping function permitting or denying expert opinion testimony on decisive issues in these cases is best made with a live expert on the witness stand subject to vigorous examination.

In the course of examining a multitude of these very similar cases involving the same fields of expertise, I have faced irreconcilably divergent expert opinions offered by witnesses with impeccable credentials, suggesting, to me, an unreasonable risk of unreliability. The danger—and to my jaded eye, the near certainty—of the admission of "junk science" looms large in this mass litigation.

The parties regularly present out-of-context statements, after-the-fact rationalization of opinions, and incomplete deposition transcripts. This, combined with the above-described practice of recycling expert testimony, objections, and the

court's prior rulings, creates the perfect storm of obfuscation. Where further clarity is necessary, I believe it is only achievable through live witnesses at trial and I will therefore reserve ruling until expert opinions can be evaluated firsthand.

IV. BSC's *Daubert* Motions

In this case, BSC seeks to limit or exclude the expert opinions of Drs. Michael Thomas Margolis, Thomas Barker, Jimmy Mays, Russell Dunn, Scott Guelcher, Richard Trepeta, Vladimir Iakovlev, Jerry Blaivas, and Bruce Rosenzweig.

BSC also filed a Motion to Exclude the Opinions and Testimony of Marvin Goldberg, Ph.D. [ECF No. 51]. BSC, however, later filed notice of its desire to have this motion withdrawn [ECF No. 90]. This motion is thus **DENIED as MOOT**.

A. Michael Thomas Margolis, M.D.

BSC seeks to exclude the testimony of Michael Thomas Margolis, M.D. Dr. Margolis is a pelvic floor surgeon and urogynecologist who offers general causation opinions in this case.

The plaintiffs do not respond to this motion, and I presume that they concede that Dr. Margolis will not testify at trial. Thus, the defendant's motion is **GRANTED**.

B. Thomas H. Barker, Ph.D.

The plaintiffs offer Dr. Barker as a biomaterials expert. He seeks to testify as to general opinions, such as those related to the biocompatibility of polypropylene mesh, mesh degradation, scar formation, mesh design, and mesh testing.

1. **Reliability**

a. Mechanical Mismatch

Dr. Barker opines that there is a mechanical mismatch between vaginal tissue and BSC mesh. I find this opinion to be unreliable. In comparing the elastic moduli of vaginal tissue to that of mesh in order to support his opinion as to a mismatch, Dr. Barker relied on a study finding six to seven kilopascals for vaginal tissue. However, he admits that he has no scientific basis for forming a kilopascal number for BSC mesh. Such an opinion rests on an unreliable basis. To the extent that Dr. Barker merely opines that vaginal tissue and polypropylene mesh are not composed of the same material, such an opinion is not helpful to a jury. Dr. Barker's opinion that a mechanical mismatch exists is **EXCLUDED**.

b. Mechanical Performance Findings

Dr. Barker's opinions on the clinical consequences resulting from the alleged mechanical mismatch between the mesh and the human body are **EXCLUDED** as unreliable as well. His opinion on the mechanical mismatch generally is excluded, and, thus, any derivative opinions are also unreliable. Such opinions are too speculative to be deemed reliable under *Daubert*.

Moreover, with respect to mesh deformation in particular, BSC challenges Dr. Barker's opinion that BSC testing revealed approximately 35 percent to 52 percent of deformation in its mesh samples. However, when questioned about this topic at his deposition, Dr. Barker admitted that he is unsure whether this testing was done exclusively on BSC products. This deposition testimony further reveals the

unreliability of Dr. Barker's methodology. BSC's motion with respect to Dr. Barker's opinions on the clinical effects of a mechanical mismatch between BSC mesh and vaginal tissue is **GRANTED**.

In conclusion, BSC's Motion to Exclude the Opinions and Testimony of Thomas H. Barker, Ph.D. is **GRANTED**.

C. Jimmy W. Mays, Ph.D.

Dr. Mays is a Distinguished Professor of Chemistry at the University of Tennessee who offers general causation opinions on the following issues: (1) the chemical structure and properties of polypropylene; (2) degradation of polypropylene by thermo-oxidative processes and in vivo; and (3) the effect of in vivo degradation on the polypropylene implant.[2]

BSC argues that Dr. Mays's opinions should be excluded because his thermogravimetric analysis ("TGA") did not replicate the in vivo environment. Dr. Mays produced certain results while testing polypropylene at very high temperatures. He then concluded that the same results will occur inside the human body at much lower temperatures, but he did not provide any explanation or support for his opinion. These derivative conclusions are not the product of reliable principles and methods. Dr. Mays failed to demonstrate a reliable connection between his TGA results and his conclusions about polypropylene degradation in the human body.

[2] As an initial matter, BSC attempts to incorporate by reference its *Daubert* objections to Dr. Mays's general causation opinions offered in *Sanchez v. Boston Scientific Corp.* BSC does not inform the court what these objections are or attach the *Sanchez* motion. Further, the expert report offered in *Sanchez* was authored by both Dr. Mays and Dr. Gido and is not identical to the report offered in the present case. Accordingly, I will not address the objections made in *Sanchez* and instead rule solely on the issues currently before me.

Accordingly, BSC's Motion to Exclude the Opinions and Testimony of Jimmy W. Mays, Ph.D. is **GRANTED**, and Dr. Mays's general causation opinions based on his TGA are **EXCLUDED**.

D. Russell Dunn, Ph.D.

Dr. Dunn is a registered professional engineer and the president and founder of Polymer Chemical Technologies LLC, a company that focuses on process and product design issues, process and product safety, and polymer product analysis.

BSC argues that Dr. Dunn is not qualified to offer opinions concerning the design, risk management, or manufacture of polypropylene mesh devices. Dr. Dunn's company, Polymer Chemical Technologies LLC, has been involved in over 200 projects focusing on polymer product design; however, none of these projects has involved a medical device. Dr. Dunn also teaches five different chemical engineering courses at Vanderbilt University; however, he has never taught a course specific to medical devices or polypropylene. Similarly, Dr. Dunn states that he has a tremendous amount of experience assessing risk through Failure Mode and Effects Analysis ("FMEA"), but then admits that he has never been involved in developing an FMEA for a medical device. Finally, Dr. Dunn has authored many publications throughout his career; however, not one of these publications examines medical devices or how polypropylene behaves as part of a medical device.

All of Dr. Dunn's opinions are premised on his belief that the polypropylene mesh in BSC's devices will undergo oxidative degradation in the body, yet Dr. Dunn admits that he is not an expert in biomaterials or biocompatibility and that he is not

qualified to opine on the way polypropylene may affect the body physiologically. I find that Dr. Dunn does not have the requisite skill, knowledge, training, education, or experience to qualify as an expert in this case, and his opinions are **EXCLUDED**. Accordingly, BSC's Motion to Exclude the Opinions and Testimony of Russell Dunn, Ph.D. is **GRANTED**.

E. Scott Guelcher, Ph.D.

Dr. Guelcher is a chemical engineer offered by the plaintiffs to opine on how the human body responds to polypropylene once it is implanted and the reactions that occur on the surface of the implant. Dr. Guelcher's opinions—to the extent they are based on Dr. Dunn's testing—are **EXCLUDED** because Dr. Dunn's testing is unreliable. Dr. Dunn's *in vitro* testing failed to follow the written protocol he relied upon in developing his test—the very protocol that Dr. Guelcher developed. Specifically, Dr. Dunn could not account for why he changed the testing solution once a week when the protocol called for changing the solution once every three days. Further, Dr. Dunn stated in his deposition that he would only use his testing to show the general behavior of polypropylene mesh in an *in vitro* oxidizing medium—not to extend what that means inside the body. Dr. Dunn's testing lacks sufficient indicia of reliability. Therefore, BSC's Motion to Exclude the Opinions and Testimony of Scott Guelcher, Ph.D. is **GRANTED**.

F. Richard Trepeta, M.D.

Richard Trepeta, M.D., is, among other things, a board-certified pathologist and a Fellow with the College of American Pathologists and the International Society

for the Study of Vulvovaginal Disease.

1. **Qualifications**

First, BSC objects to Dr. Trepeta's opinion testimony on the properties of polypropylene mesh. Given Dr. Trepeta's knowledge and experience as an anatomical and clinical pathologist, I find him qualified to testify about mesh degradation, mesh shrinkage, and mesh migration, and I therefore **DENY** BSC's motion in this respect.

Second, BSC objects to Dr. Trepeta's testimony on the human clinical response to mesh implants. Dr. Trepeta's extensive experience and knowledge in the field of pathology qualify him to submit these opinions. Part of pathology involves reaching a diagnosis through clinical and pathologic correlation. Dr. Trepeta frequently engages in this process by providing clinical consultations to physicians, which require him to examine clinical information (through specimens, reports, or physician findings) and reach a pathologic diagnosis about a patient. Dr. Trepeta's understanding and application of the pathologic process qualify him to opine on the causal relationship between transvaginal mesh implantation and tissue response. Therefore, I **DENY** BSC's motion as to Dr. Trepeta's qualifications on this point.

2. **Reliability and Relevance**

BSC raises two objections to the reliability and relevance of Dr. Trepeta's opinion testimony.

a. Reliability

BSC contends that Dr. Trepeta's method of using pathology reports to formulate his opinions is unreliable. Dr. Trepeta used various resources to reach his

expert opinion: (1) he has studied over fifty mesh explant samples in his private practice; (2) he has studied the medical literature on mesh implantation and determined that his pathological findings corresponded with the published research on mesh erosion and exposure in the vaginal wall; and (3) he has reviewed twenty-four pathology reports that he received from the plaintiffs' counsel and ascertained that the pathology reports of excised Boston Scientific products are consistent with the acute, sub-acute, and chronic categories of the disease process.

Dr. Trepeta's review of the pathology reports has a fatal deficiency—it lacked standards to govern the process of selecting the sample of pathology reports to be evaluated. The plaintiffs do not explain how or why they chose these twenty-four reports for Dr. Trepeta's review, and without such an explanation, I have no way of assessing the potential rate of error or the presence of bias. Accordingly, Dr. Trepeta's opinions derived solely from his review of the twenty-four pathology reports are **EXCLUDED**. BSC is free to cross-examine Dr. Trepeta at trial to ensure the basis of his opinions is consistent with the court's ruling.

b. Litigation Driven

BSC argues Dr. Trepeta's opinions are unreliable because they are litigation driven. I will not exclude an expert on the sole basis that the opinion arose during litigation, so long as it is otherwise reliable. BSC's Motion is **DENIED** on this point.

In conclusion, Dr. Trepeta's general causation opinions are admitted except for his opinions based on the pathologic reports selected by the plaintiffs' counsel for his review, which are excluded. Accordingly, BSC's Motion to Exclude the Opinions and

Testimony of Dr. Trepeta is **GRANTED in part** and **DENIED in part**.

G. Vladimir Iakovlev, M.D.

Dr. Iakovlev is an anatomical pathologist and director of Cytopathology at the Department of Laboratory Medicine at St. Michael's Hospital in Toronto, Canada.

1. General Causation

BSC contends that this court should exclude Dr. Iakovlev's opinions on specimens other than the plaintiffs'. Dr. Iakovlev's general causation opinions are based largely on his examination of the mesh explant samples in his personal data pool. However, Dr. Iakovlev provides no information on how the mesh explants were chosen or prepared for examination. Dr. Iakovlev testified that plaintiffs' counsel provided approximately 70 percent of the transvaginal mesh explants, but he does not know how those explants were chosen or what methodology counsel employed.

Accordingly, BSC's motion on this matter is **GRANTED**, and Dr. Iakovlev's general causation opinions based on his data pool are **EXCLUDED**.

2. Specific Causation

BSC also challenges Dr. Iakovlev's specific causation opinions related to Ms. Sederholm. In the past, the court has allowed Dr. Iakovlev to offer specific causation opinions in cases where "[h]e reviewed clinical records, examined explanted specimens, considered possible causes of pain, and came to a diagnostic conclusion." *Eghnayem v. Bos. Sci. Corp.*, 57 F. Supp. 3d at 712. In this case, however, Dr. Iakovlev's specific causation opinions are unreliable—and are therefore **EXCLUDED**—because he completely failed to consider other possible causes of pain. *See Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 202 (4th Cir. 2001) ("[I]f an expert

utterly fails to consider alternative causes . . . a district court is justified in excluding the expert's testimony.").

In conclusion, BSC's Motion to Strike and Exclude the Opinions and Testimony of Vladimir Iakovlev, M.D. is **GRANTED**.

H. Jerry Blaivas, M.D.

Dr. Blaivas is a pelvic surgeon and urologist. The plaintiffs offer Dr. Blaivas to opine as to general causation. He renders several opinions, including those related to the complications associated with polypropylene mesh slings and the Obtryx, the safety and efficacy of synthetic slings as compared to non-mesh procedures, and BSC's warnings to physicians and patients.

1. **Opinion that Polypropylene Mid-Urethral Slings Are Not Safe in the Treatment of SUI**

BSC challenges Dr. Blaivas's opinion that polypropylene mid-urethral slings are not safe in the treatment of SUI. I **EXCLUDE** Dr. Blaivas's opinion because Dr. Blaivas applied standards different than those he applies in his medical practice. In his deposition, Dr. Blaivas was confronted with a statement he had previously made in a peer-reviewed article that contradicts his safety opinion proffered in this case. Dr. Blaivas explains that "I phrase my words differently in the peer-reviewed literature than I do in the legal literature because it's two different sets of rules." Blaivas Dep. 391:20–24, Dec. 15, 2014. He states, "I can offer a different opinion with a reasonable degree of medical certainty than I can in the peer-reviewed literature which requires, in my judgment, a higher degree of certainty than a reasonable degree." *Id.* at 391:14–19.

The above deposition testimony plainly reveals that Dr. Blaivas employed less intellectual rigor in forming this opinion as an expert witness than he employs when writing studies in his field. Such admission renders Dr. Blaivas's methodology unreliable. As a result, BSC's motion with respect to this opinion is **GRANTED**.

2. Opinion on Design of Polypropylene Mesh Slings

Next, BSC challenges Dr. Blaivas's opinion on the design of polypropylene mesh slings. I agree with BSC that Dr. Blaivas lacks qualifications to be deemed an expert in the design of a medical device. The plaintiffs contend that Dr. Blaivas's surgical experience with similar slings renders him qualified. This experience alone, however, insufficiently establishes his design qualifications. Thus, his opinions related to product design are **EXCLUDED**.

3. BSC Alleges that Dr. Blaivas Seeks to Offer Opinions Outside Area of Expertise

BSC argues that Dr. Blaivas seeks to offer opinions on mesh shrinkage, degradation, and the Material Safety Data Sheets (MSDS) that are outside his area of expertise. Above, I exclude Dr. Blaivas's opinion that polypropylene mid-urethral slings are not safe in the treatment of SUI on reliability grounds. Therefore, I need not address Dr. Blaivas's qualifications on shrinkage and degradation.

As for the MSDS, BSC seeks to exclude Dr. Blaivas's opinion that the polypropylene mesh used in the Obtryx, Obtryx Curved, and Obtryx Halo was never meant to be implanted inside the human body per the MSDS. The plaintiffs fail to respond to this argument, and I presume that the plaintiffs concede that Dr. Blaivas will not offer such an opinion at trial. I decline to raise counterarguments on the

plaintiffs' behalf. Thus, BSC's motion with respect to Dr. Blaivas's MSDS opinion is **GRANTED**.

4. Specific Causation

Although BSC argues that Dr. Blaivas's specific causation opinions should be excluded, Dr. Blaivas is not a specific causation expert in this case. Therefore, BSC's motion with respect to this matter is **DENIED**.

In conclusion, BSC's Motion to Exclude the Opinions and Testimony of Jerry Blaivas, M.D. is **GRANTED in part** and **DENIED in part**.

I. Bruce Rosenzweig, M.D.

Dr. Bruce Rosenzweig is a urogynecologist and a professor of obstetrics and gynecology in Chicago, Illinois. In this case, the plaintiffs offer Dr. Rosenzweig as a general causation expert on the properties of the polypropylene mesh used in the Advantage sling product ("Advantage"), its reaction when implanted in the body, and the possible complications associated with its use to treat SUI.

1. Biochemical Properties of Polypropylene

First, BSC argues that because Dr. Rosenzweig has no background in biochemistry or toxicology, he is not qualified to render opinions on the biochemical properties of polypropylene. Dr. Rosenzweig has performed over a thousand pelvic floor surgeries, hundreds of which dealt with synthetic mesh. And as he explained during his deposition, "I have explanted mesh. I have seen degraded mesh. I've seen hardened, brittled, fragmented mesh upon removal of mesh." Rosenzweig Dep. 24:23–25:1, Nov. 24, 2014. Furthermore, Dr. Rosenzweig has read "close to the 2,000 papers

that have been generated on midurethral slings." *Id.* at 19:6–11. Dr. Rosenzweig's established background and skill in pelvic surgery, polypropylene, and the complications associated with degradation qualify him to opine on the degradation process. Any gaps in Dr. Rosenzweig's knowledge go to his credibility, not his admissibility as an expert.

BSC also contends that Dr. Rosenzweig has not provided a reliable basis for his opinions regarding the properties of polypropylene mesh and has instead solely relied on a gross examination of his patients. I disagree. In addition to the examination of his patients over the past twenty years, Dr. Rosenzweig has consulted and relied upon scientific and medical literature concerning the degradation of polypropylene in reaching his opinion that mesh degrades. Dr. Rosenzweig's methodology is reliable.

For these reasons, I find Dr. Rosenzweig qualified to opine on mesh degradation and the properties of polypropylene, and I further find that his opinions are supported by a reliable methodology. Therefore, I **DENY** BSC's motion on this matter.

2. Product Design

BSC next argues that Dr. Rosenzweig is not qualified to opine on the design of the Advantage because he has little experience designing, marketing, or drafting medical device labels, and he has no experience in designing implantable devices like vaginal mesh. Therefore, in BSC's view, Dr. Rosenzweig's opinions on the suitability of mesh as a permanent implant should be excluded.

Although Dr. Rosenzweig has never designed vaginal mesh devices, he has considerable familiarity with their structure and use. First, over the course of his career as a pelvic surgeon, he has accumulated an abundance of knowledge about the use of various surgical procedures in the treatment of SUI, including the implantation of midurethral slings like the Advantage. Second, Dr. Rosenzweig received thorough training on the implantation of sling products in pelvic repair. Third, Dr. Rosenzweig has performed these procedures countless times. And finally, Dr. Rosenzweig has invented a catheter device, which reinforces his background in the design and use of surgical products. This knowledge, training, and experience with product design, specifically the design of BSC's midurethral slings, qualify Dr. Rosenzweig to opine on the design of the Advantage and the polypropylene used to construct it.

Furthermore, contrary to BSC's contentions, Dr. Rosenzweig has a reliable basis for his opinions on the Advantage product design. He considered more than internal corporate documents in arriving at his opinion on the design of the Advantage, incorporating his experience and citing to relevant scientific literature. This detailed examination of the literature in light of his first-hand experience with mesh devices satisfies the reliability requirements of *Daubert*.

Accordingly, I decline to exclude Dr. Rosenzweig's opinions on product design, and BSC's motion on this point is **DENIED**.

3. Product Testing

Next, BSC asks this court to exclude Dr. Rosenzweig's opinions on the testing of mesh products, including his opinions that BSC should have undergone further

and more extensive testing of the mesh products. According to BSC, Dr. Rosenzweig lacks the qualifications to opine on these matters. While Dr. Rosenzweig has years of experience operating with polypropylene mesh products, his expert report does not convey any similar experience, education, or knowledge about the appropriate testing a medical device manufacturer should perform on its products prior to sale. Therefore, I find Dr. Rosenzweig unqualified to testify on the adequacy or inadequacy of BSC's product testing. This aspect of BSC's motion is thus **GRANTED**.

4. Advantage Directions for Use ("DFU")

BSC also argues that because Dr. Rosenzweig does not have experience personally drafting product labels, he is unqualified to opine on the adequacy of the warnings contained in the Advantage DFU. I have previously considered whether experience as a urogynecologist can qualify a witness to opine on the sufficiency of a DFU, and my conclusion has been affirmative to a certain extent. *See Wise v. C. R. Bard, Inc.*, No. 2:12-CV-01378, 2015 WL 521202, at *14 (S.D. W. Va. Feb. 7, 2015) (quoting *In re Yasmin & Yaz (Drospirenone) Prods. Liab. Litig.*, 2011 WL 6301625, at *11 (S.D. Ill. Dec. 16, 2011)). Without experience or background in the legal requirements for medical device warnings, Dr. Rosenzweig is qualified to opine on the content of the DFU only to the extent that his opinions fit within the comparison described in *In re Yasmin*. Trusting that Dr. Rosenzweig's testimony at trial will be limited accordingly, I **DENY** BSC's motion on this matter.

5. Link Between Cancer and Polypropylene Mesh

During his deposition, Dr. Rosenzweig offered the opinion that there is "an

association" between cancer and polypropylene. Rosenzweig Dep. 147:4–9. BSC moves to exclude this opinion as irrelevant and prejudicial. The plaintiffs concede that Dr. Rosenzweig will not testify regarding these opinions. All of Dr. Rosenzweig's opinions on this matter are therefore **EXCLUDED**.

6. Material Safety Data Sheet ("MSDS") for Polypropylene

Finally, BSC objects to Dr. Rosenzweig's opinion that the Advantage should not be used in the body because the manufacturer of the raw polypropylene has included in its MSDS a medical application caution stating that material should not be permanently implanted in the body. BSC claims that this opinion is irrelevant.

Dr. Rosenzweig's opinion about the MSDS deals with subject matters about which he is not qualified to testify. Specifically, Dr. Rosenzweig concludes that BSC did not perform the necessary testing that it should have to investigate the MSDS warning. As explained above, Dr. Rosenzweig lacks the experience and knowledge necessary to opine on what testing a manufacturer should perform on its products. These opinions, therefore, are **EXCLUDED**.

In sum, BSC's Motion to Exclude the General Causation Testimony of Dr. Bruce Rosenzweig [ECF No. 33] is **GRANTED in part** and **DENIED in part**.

BSC also filed another concurrent motion to exclude Dr. Rosenzweig's testimony [ECF No. 42]. In this second motion, BSC argues that Dr. Rosenzweig bases much of his opinions on data concerning the Advantage mesh products, and then applies that data to cases concerning other mesh products. In the instant case, however, the mesh product at issue is an Advantage product. Thus, I **DENY** BSC's

motion to exclude on this point.

BSC also challenges the reliability of Dr. Rosenzweig's case-specific opinions because he did not examine the plaintiffs nor speak with the treating physicians. Dr. Rosenzweig did not have to perform a physical examination of the plaintiffs to reach a reliable opinion about specific causation. *See Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 203 (4th Cir. 2001) ("[A] physician may reach a reliable differential diagnosis without personally performing a physical examination."). Nor is Dr. Rosenzweig's opinion unreliable merely because he relied on other examination records. *See Kannankeril v. Terminix Int'l, Inc.*, 128 F.3d 802, 807 (3d Cir. 1997), ("[A] physician may reach a reliable differential diagnosis without himself performing a physical examination, particularly if there are other examination results available."). I find BSC's argument unpersuasive, and I **DENY** its motion to exclude with respect to Dr. Rosenzweig's specific causation opinion.

Therefore, BSC's Motion to Exclude the Testimony of Dr. Rosenzweig [ECF No. 42] is **DENIED**.

V. The Plaintiffs' *Daubert* Motions

In this case, the plaintiffs seek to limit or exclude the expert opinions of Drs. Gary L. Winn, Christine Brauer, Stephen Spiegelberg, Stephen F. Badylak, Ricardo Caraballo, and Brian Feagins.

A. Gary L. Winn, Ph.D.

Dr. Winn is a professor in Industrial and Management Systems Engineering in the Safety Management program at West Virginia University. Dr. Winn offers expert opinions with regard to the nature and purpose of an MSDS generally, and

specifically as to the MSDS for the polypropylene used by BSC in the manufacture of its pelvic mesh products. The plaintiffs argue that Dr. Winn's opinions should be excluded entirely, consistent with this court's decisions in *Tyree* and *Eghnayem* because his expert report is identical to the reports filed and excluded in those two cases.[3] BSC has not presented any new arguments to convince me that Dr. Winn is warranted as an independent expert. However, I acknowledge the potential need for rebuttal testimony based on what the plaintiffs present at trial. Accordingly, I **RESERVE** ruling on the admissibility of Dr. Winn's expert opinions for trial.

B. Christine Brauer, Ph.D.

Dr. Brauer is the President of Brauer Device Consultants LLC, where she provides consulting services to the medical device industry regarding FDA regulatory requirements. The plaintiffs seek to exclude both of Dr. Brauer's expert reports filed on November 21, 2014. The first report ("FDA report") focuses on the FDA regulatory framework for surgical devices, and the second report ("supplemental report") focuses on industry standards that a manufacturer of a medical device must meet. I have

[3] In *Tyree*, I ruled as follows:

> In his expert report, Dr. Winn describes (1) the development of the hazard communication standard; (2) the standardization of the content of MSDSs; and (3) uses of MSDSs in the field. Dr. Winn concludes that raw polypropylene is not hazardous based on anecdotal evidence involving other MSDSs; and therefore, the 2004 Chevron Phillips MSDS is extraneous. Although I believe that the warning provided in the MSDS is relevant, I do not believe an expert is required to discuss MSDSs generally or the issue of whether polypropylene requires an MSDS because of its hazardous nature. A narrative review of the history and development of MSDSs and who uses them in the field is not helpful to the jury. The pertinent issue is that the MSDS contained a warning (Medical Application Caution) allegedly not heeded by BSC, not that an MSDS itself existed. This warning from the supplier could have taken any form. Accordingly, I **FIND** that Dr. Winn's opinions regarding MSDSs should be excluded in their entirety.

2014 WL 5320566, at *63; *see also Eghnayem*, 2014 WL 5461991, at *61 (quoting *Tyree*).

repeatedly and thoroughly considered the admissibility of the FDA's 510(k) process, and I have consistently found that the 510(k) process does not relate to safety or efficacy. Therefore, the parties may not present evidence regarding the 510(k) clearance process or subsequent FDA enforcement actions. Accordingly, the plaintiffs' motion with regard to Dr. Brauer's FDA report is **GRANTED**, and her opinions set forth in that report are **EXCLUDED**.

With regard to the supplemental report, the plaintiffs contend that it is nothing more than the FDA report under a different cloak. I agree. Reading the two reports side by side, it appears that Dr. Brauer "supplemented" her report by removing references to the FDA and substituting the term "industry standard" instead. This "industry standard" clearly describes the FDA 510(k) process, which Dr. Brauer admits in her deposition. There is far too much overlap between Dr. Brauer's FDA report and supplemental report to avoid a regulatory mini-trial, which I have repeatedly and consistently held would confuse and mislead the jury. Accordingly, the plaintiffs' Motion to Exclude or Limit the Testimony of Christine Brauer, Ph.D. is **GRANTED**, and Dr. Brauer's opinions are **EXCLUDED** in their entirety.

C. Stephen Spiegelberg, Ph.D.

Dr. Spiegelberg is the president and co-founder of Cambridge Polymer Group Inc., where he directs a team of scientists who perform contract research, analytical testing, and device development for the biomedical and polymer communities.

1. Position Statements

First, the plaintiffs argue that Dr. Spiegelberg's opinions regarding position statements should be excluded because (1) they are not contained in his expert report;

(2) he is not qualified to offer such opinions; and (3) he lacks any reliable methodology. Upon review, I agree with BSC that Dr. Spiegelberg does not in fact offer the opinions the plaintiffs seek to exclude. Accordingly, the plaintiffs' motion with regard to position statements is **GRANTED**.

2. FDA

Next, the plaintiffs contend that Dr. Spiegelberg is unqualified to opine on the FDA 510(k) clearance process and that such opinions should be excluded as irrelevant. In response, BSC concedes that Dr. Spiegelberg will not offer opinions on the FDA 510(k) clearance process. Accordingly, the plaintiffs' motion with regard to the FDA is **GRANTED.**

BSC limits its concession by arguing that Dr. Spiegelberg is qualified to opine on ISO standards based on his experience in the field of medical device analysis and design. I agree. Dr. Spiegelberg's current work revolves around medical device development and consultation. He is also the Task Force Chairman for the American Society for Testing and Materials ("ASTM"), which establishes standards involving the cleanliness of biomedical devices and characterization methods for polymers. Consulting on the development of new medical products requires familiarity with the applicable industry standards. Therefore, to the extent Dr. Spiegelberg intends to opine on ISO standards without referencing the FDA, I find him qualified to do so. Accordingly, the plaintiffs' motion with regard to Dr. Spiegelberg's qualifications is **DENIED**.

3. Black Specks or Spots

Next, the plaintiffs argue that Dr. Spiegelberg's opinions regarding black specks in BSC's mesh are unfounded and unreliable. In his expert report, Dr. Spiegelberg states that the "black spots" are actually reflections of light on the curves of the mesh when pictures are taken, rather than inclusions or defects in the mesh. The plaintiffs contend that Dr. Spiegelberg's findings are unreliable because he did not review the photographs supplied by the plaintiffs' expert, Dr. Dunn, nor did he take his own photographs. Whether Dr. Spiegelberg took his own photographs does not sufficiently undermine the reliability of his analysis here. Challenges to Dr. Spiegelberg's ultimate conclusion with regard to the nature of the black spots are better suited for cross-examination. Accordingly, the plaintiffs' motion with regard to black specks or spots is **DENIED**.

4. FTIR and EDS

Last, the plaintiffs seek to limit Dr. Spiegelberg's general causation opinions based on his Fourier Transform Infrared Spectroscopy ("FTIR") and Electron Dispersive Spectroscopy ("EDS") testing. However, the plaintiffs point out that Dr. Spiegelberg's admissions regarding the limitations of these testings may also be grounds for cross-examination and thus seeks only qualification or explanation of the limitations inherent to the testing in order to avoid misleading or confusing the jury. The plaintiffs will have the opportunity to adequately highlight these limitations at trial upon cross-examination. Accordingly, the plaintiffs' motion with regard to Dr. Spiegelberg's FTIR and EDS testing is **DENIED**.

In sum, the plaintiffs' Motion to Exclude the Testimony and Opinions of Dr.

Stephen Spiegelberg, Ph.D. is **GRANTED in part** and **DENIED in part**.

D. Stephen F. Badylak, D.V.M., Ph.D., M.D.

Dr. Badylak is the Deputy Director of the McGowan Institute for Regenerative Medicine, Director of the Center for Preclinical Studies, and a tenured professor with the Department of Surgery at the University of Pittsburgh.

1. Risk-Benefit Analysis or Safety and Efficacy

The plaintiffs contend that Dr. Badylak should be precluded from opining on the safety and efficacy of polypropylene mesh devices because he has not reviewed the applicable scientific literature and he has no clinical experience using these devices. Dr. Badylak's expert report indicates that he reviewed more than 200 relevant scientific publications, including more than twenty publications evaluating the safety and efficacy of BSC devices. Furthermore, Dr. Badylak explains that he is more familiar with the body of literature reviewing the safety and efficacy of surgical mesh generally, versus literature specific to any one device. This explanation does not undermine his qualifications but instead clarifies his approach. If there are certain device-specific publications that Dr. Badylak failed to review in preparing his expert report, the plaintiffs are free to ask him about those publications on cross-examination.

Similarly, the plaintiffs' arguments regarding Dr. Badylak's clinical experience are also without merit. Dr. Badylak has extensive experience in the field of biomaterials, including the design of implantable surgical mesh devices. Accordingly, the plaintiffs' motion with regard to Dr. Badylak's safety and efficacy opinions is **DENIED**.

2. Degradation

The plaintiffs argue that Dr. Badylak's opinions with regard to oxidative degradation based on the scientific literature are unreliable because he contradicted himself during his deposition by acknowledging the "phenomenon" of oxidative reactions. However, the plaintiffs omit Dr. Badylak's subsequent testimony, where he states that he does not believe that oxidative reactions at the surface of polypropylene results in the degradation that causes further problems. Upon review of the deposition, I do not find Dr. Badylak's testimony sufficiently contradictory to undermine the reliability of his expert opinions. Accordingly, the plaintiffs' motion on this point is **DENIED**.

The plaintiffs' Motion to Exclude the Opinions and Testimony of Stephen F. Badylak, D.V.M., Ph.D., M.D. is thus **DENIED**.

E. Brian A. Feagins, M.D.

Dr. Brian Feagins is a board-certified urologist and has been focusing his practice on incontinence, voiding dysfunctions, and pelvic pain for over twenty years. He is a member of several urogynecological associations and has performed at least 4,000 polypropylene mid-urethral sling surgeries during his career.

1. Safety and Efficacy

The plaintiffs argue that Dr. Feagins's opinions concerning the safety and efficacy of the Advantage sling are based on an unreliable foundation because Dr. Feagins relies on data and studies about other TVT slings. BSC counters that this data is reliable because the Advantage slings contain mesh that is substantially similar to mesh used in other TVT slings.

I find there is a "valid scientific connection" between data and studies about other mid-urethral polypropylene slings and the Advantage sling. *See, e.g., Mathison v. Bos. Sci. Corp.*, No. 2:13-cv-05851, 2015 WL 2124991, at *19 (S.D. W. Va. May 6, 2015) (allowing studies about SUI products to be admitted in the expert testimony regarding a different SUI product). Accordingly, the plaintiffs' motion on this point is **DENIED**.

2. Mesh Product's Directions for Use ("DFU")

Next, the plaintiffs argue that Dr. Feagins is not qualified to render expert opinions on the adequacy of the Advantage's DFU because Dr. Feagins has no knowledge of the regulatory or industry requirements of a medical device's DFU. BSC argues that Dr. Feagins does not need to be a "warnings expert" to testify that the DFU is adequate.

Without additional expertise in the specific area of product warnings, however, a urologist, like Dr. Feagins, is not qualified to opine on the adequacy of the DFU merely based on risks he observed in his own practice. *Frankum v. Bos. Sci. Corp.*, No. 2:12-cv-904, 2015 WL 1976952, at *34 (S.D. W. Va. May 1, 2015). Accordingly, Dr. Feagins's opinions about the Advantage DFU are **EXCLUDED**.

3. Mesh Degradation, Shrinkage, and Contraction

First, the plaintiffs challenge Dr. Feagins's qualification to opine on the physical properties of mesh because he is not an expert in biomedical engineering and has not studied chemical polymers. However, his extensive clinical experience surgically treating pelvic floor disorders with mesh, as well as his review of the

medical and scientific literature adequately qualify him to opine on polypropylene. Accordingly, the plaintiffs' motion as to Dr. Feagins's qualifications is **DENIED**.

Next, the plaintiffs challenge the reliability of Dr. Feagins's opinion on the physical properties of mesh. Dr. Feagins claims he based this opinion on his clinical experience, during which he did not observe evidence of such mesh properties, and upon review of medical and scientific literature.

The advisory committee notes to Rule 702 state:

> If the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts. The trial court's gatekeeping function requires more than simply "taking the expert's word for it."

Fed. R. Evid. 702 advisory committee's note to 2000 amendment (citing *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1319 (9th Cir. 1995) ("We've been presented with only the expert's qualifications, their conclusions and their assurances of reliability. Under *Daubert*, that's not enough.")).

Yet the Fourth Circuit appears more willing to "take the expert's word for it" so long as the expert has demonstrated that he or she has experience in a field writ large. *See, e.g., Eskridge v. Pac. Cycle, Inc.*, 556 F. App'x 182, 190–91 (4th Cir. 2014) (unpublished) (finding a bicycle engineer's experience with "hundreds of cases of accidents" and "decades of experience in the industry in general" provided a reliable basis to testify about whether bicycle purchasers read warnings and dismissing concerns that the bicycle expert's testimony was nothing more than personal opinion because of his "years of experience" and assurance that all of his opinions were "to a

reasonable degree of engineering certainty").

On the one hand, Dr. Feagins has based his opinions on his extensive clinical experience and a review of the medical and scientific literature, which, in the abstract, are reasonable bases from which to form an expert opinion. *See Kumho*, 526 U.S. at 156 ("[N]o one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience.").

On the other hand, the court does not have enough information to judge the reliability or relevance of these particular clinical observations—as distinguished from experience examining mesh explants. Perhaps Dr. Feagins did not observe evidence of mesh contraction because he was not looking. Or perhaps his method of identifying and tracking the complications at issue is not scientifically sound. Additionally, sweeping statements about support within the medical community or medical literature can be difficult to assess. Although the expert report indicates Dr. Feagins reviewed an extensive list of literature in forming his opinions generally, the court is directed to minimal specific support for the statements at issue or detail about Dr. Feagins's methodology.

In this specific context, I am without sufficient information at this time to draw the fine line between reliable and unreliable expert testimony on physical mesh properties based primarily on a doctor's clinical observations, or lack thereof. Accordingly, I **RESERVE** ruling until further testimony may be offered and evaluated firsthand at trial.

4. FDA's Stance on Mesh Slings

The plaintiffs challenge opinions offered by Dr. Feagins regarding the FDA's opinions and stances on the Advantage mesh products.

BSC concedes that Dr. Feagins will not offer opinions on the FDA 510(k) clearance process, but will cite to other FDA findings to support his opinion that the mesh product is safe and effective. I have repeatedly held that the probative value of FDA evidence is substantially outweighed by the risk of jury confusion. Therefore, to the extent Dr. Feagins seeks to offer other expert opinions on the FDA, such opinions are **EXCLUDED**. Accordingly, the plaintiffs' motion on this point is **GRANTED**.

5. Advantage Sling as the "Gold Standard"

Next, the plaintiffs challenge the reliability of Dr. Feagins's opinion that the Advantage is the "gold standard" in the treatment of stress urinary incontinence because he bases this opinion on data from other mesh products.

As explained above regarding data about other sling products, this does not sufficiently undermine the reliability of Dr. Feagins's opinions. Accordingly, the plaintiffs' motion on this point is **DENIED**.

6. AUGS/SUFU Position Statement

The plaintiffs also seek to exclude Dr. Feagins's characterization and repetition of position statements by the American Urogynecological Society and the Society for Urodynamics and Female Urology that full length mid-urethral slings, including the Advantage, are safe, effective, and the gold standard treatment for SUI repair. The plaintiffs argue that these opinions must be excluded because Dr. Feagins has no knowledge of the process or manner in which the position statements were drafted.

As I have previously indicated in these MDLs, position statements are not expert opinions. *See, e.g.*, *Tyree v. Bos. Scientific Corp.*, 54 F. Supp. 3d at 574; *and Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 731–32 (S. D. W. Va. 2014). Therefore, I will not address the admissibility of this testimony at this time. Accordingly, I **RESERVE** ruling on the admissibility of this testimony for trial.

7. Qualifications to Offer Expert Testimony on Advantage Sling Design

Next, the plaintiffs argue that Dr. Feagins's conclusory opinions regarding the design of the Advantage sling should be excluded because he lacks the qualifications to discuss the structural make-up of the mesh product. The plaintiffs do not, however, explain which conclusory opinions regarding the design of the Advantage sling that they are referencing and the court could not find any design opinions in the pages cited. Accordingly, the plaintiffs' motion on this point is **DENIED**.

8. Specific Causation

Next, the plaintiffs argue that Dr. Feagins's specific causation opinions should be excluded as unreliable because Dr. Feagins did not conduct an adequate differential diagnosis and concludes that Ms. Sederholm's pain was not caused by the Advantage without providing a sufficient basis for this opinion.

BSC contends that Dr. Feagins's specific causation opinions are based on reliable facts and data. Dr. Feagins's report, however, provides little more than unsubstantiated conclusory statements. The report fails to provide any meaningful bases or support for Dr. Feagins's specific causation opinions. Therefore, I **GRANT** the plaintiffs' motion on this matter.

In short, the plaintiff's Motion to Exclude the Opinions and Testimony of Dr. Feagins is **GRANTED in part**; **DENIED in part**; and **RESERVED in part**.

F. Ricardo Caraballo, M.D.

Dr. Caraballo is a board-certified urogynecologist whose practice focuses on female pelvic medicine and reconstructive surgery. Dr. Caraballo has extensive experience implanting and removing pelvic mesh devices used for the treatment of SUI.

1. Safety and Efficacy

The plaintiffs first argue that Dr. Caraballo's opinions on the safety and efficacy of the Advantage sling should be excluded because they are not supported by the available medical and scientific literature.[4] According to the plaintiffs, Dr. Caraballo's opinions should be excluded because Dr. Caraballo was unable to cite to a single study that compared the Advantage to other polypropylene retropubic slings. According to Dr. Caraballo's deposition testimony, however, he states that no study specifically compares the Advantage to other polypropylene meshes. Caraballo Dep. 62:14–64:21, Jan. 10, 2015. Dr. Caraballo cited to numerous scientific articles and studies to support his contention that polypropylene mesh slings are generally safe and efficacious. To the extent that Dr. Caraballo is unable to provide scholarship directly comparing the safety and efficacy of the Advantage to that of other mesh devices, such matters go to the weight of his opinion, not its admissibility.

The plaintiffs also argue that Dr. Caraballo's opinions concerning the

[4] The plaintiffs likewise challenge Dr. Caraballo's opinions as to the Advantage Fit device; however, the Advantage Fit is not at issue in this case.

Advantage's safety and efficacy cannot be supported by his independent knowledge or his clinical experiences. I disagree. Dr. Caraballo has implanted over 1,000 Advantage or Advantage Fit devices, in addition to implanting other pelvic mesh devices. Dr. Caraballo has also published multiple articles on polypropylene mesh for the treatment of pelvic floor disorders. Dr. Caraballo's experience and review and contribution to the medical literature provide a reliable basis for his opinions on this issue. To the extent the plaintiffs believe Dr. Caraballo's experience or knowledge is lacking, she may inquire as to these matters during cross-examination. The plaintiffs' motion on this point is **DENIED**.

2. Advantage DFU

The plaintiffs next argue that Dr. Caraballo is unqualified to offer opinions on the Advantage's DFU. The plaintiffs state that, not only does Dr. Caraballo admit that he is not an expert in this area, he does not even use the DFU in his practice. The plaintiffs point out that Dr. Caraballo admitted that he did not consult the DFU prior to implanting the Advantage in his patients or before removing the device. Dr. Caraballo opines that the DFU adequately warns of all of the risks and complications that he has personally observed in his practice and that "these devices are not associated with any new risks to patients that I [have] not previously encountered with other pelvic floor surgeries." Caraballo Report 6.

In the past, I allowed a doctor to testify that the DFU was inadequate because it failed to warn against risks the doctor observed in his or her own practice. In contrast, now I must determine whether the same kind of doctor is instead qualified

to offer his expert opinion that the warnings were in fact adequate. There is a clear distinction. The plaintiffs' experts observed certain risks and complications in their practice and then sought to opine that those risks should have been included in the product warnings. In the present case, BSC's experts have observed certain risks and complications in their practice, which are warned of in the DFU, and therefore deduce that there are no other possible risks or complications that should have been included. The plaintiffs' experts address a discrete risk which they have personally observed, while BSC's experts' opinions attempt to encompass all possible risks, none of which they have personally observed. Accordingly, I **FIND** that without additional expertise in the specific area of product warnings, a doctor, such as a urologist or urogynecologist, is not qualified to opine that a product warning was adequate, merely because it included risks he has observed in his own practice.

Dr. Caraballo does not possess any additional expertise in the specific area of product warnings that would qualify him to offer opinions regarding whether the DFU adequately warns patients of any new risks to patients that he has not previously encountered in his practice. Such opinions are **EXCLUDED**. However, to the extent that the DFU provides warnings specific to the plaintiff's alleged injuries, Dr. Caraballo is qualified to opine on the adequacy of those warnings. Accordingly, the plaintiffs' motion on this point is **GRANTED in part and DENIED in part.**

3. Properties of Polypropylene

The plaintiffs next argue that Dr. Caraballo should not be permitted to offer opinions on the properties of polypropylene, specifically foreign body reactions,

shrinkage, and degradation. The plaintiffs challenge Dr. Caraballo's qualifications and the reliability of his opinions.

Dr. Caraballo is an experienced urogynecologist, and he has performed many surgeries implanting and removing polypropylene mesh devices used for the treatment of SUI. I have generally found that such experience qualifies physicians to opine on the properties of polypropylene irrespective of a lack of specialized knowledge of biomaterials. I likewise find that Dr. Caraballo's experience with polypropylene mesh devices sufficiently qualifies him to offer opinions regarding foreign body reaction, shrinkage, and degradation. The plaintiffs' motion as to this point is **DENIED**.

The plaintiffs challenge the reliability of Dr. Caraballo's opinion on the physical properties of mesh—specifically that the device in question does not degrade, shrink, or cause a foreign body reaction. Dr. Caraballo claims he based this opinion on his clinical experience, during which he did not observe evidence of such mesh properties, and upon relevant medical and scientific literature.

The advisory committee notes to Rule 702 state:

> If the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts. The trial court's gatekeeping function requires more than simply "taking the expert's word for it."

Fed. R. Evid. 702 advisory committee's note to 2000 amendment (citing *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1319 (9th Cir. 1995) ("We've been presented with only the expert's qualifications, their conclusions and their assurances of

reliability. Under *Daubert*, that's not enough.")).

Yet the Fourth Circuit appears more willing to "take the expert's word for it" so long as the expert has demonstrated that he or she has experience in a field writ large. *See, e.g., Eskridge v. Pac. Cycle, Inc.*, 556 F. App'x 182, 190–91 (4th Cir. 2014) (unpublished) (finding a bicycle engineer's experience with "hundreds of cases of accidents" and "decades of experience in the industry in general" provided a reliable basis to testify about whether bicycle purchasers read warnings and dismissing concerns that the bicycle expert's testimony was nothing more than personal opinion because of his "years of experience" and assurance that all of his opinions were "to a reasonable degree of engineering certainty").

On the one hand, Dr. Caraballo has based his opinions on his extensive clinical experience and a review of the medical and scientific literature; in the abstract, these are reasonable bases from which to form an expert opinion. *See Kumho*, 526 U.S. at 156 ("[N]o one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience.").

On the other hand, the court does not have enough information to judge the reliability or relevance of these particular clinical observations—as distinguished from experience examining mesh explants. Perhaps Dr. Caraballo did not observe evidence of mesh degradation and shrinkage because he was not looking. Or perhaps his method of identifying and tracking the complications at issue is not scientifically sound. Additionally, sweeping statements about support within the medical community or medical literature can be difficult to assess. Although the expert report

indicates Dr. Caraballo reviewed an extensive list of literature in forming his opinions generally, the court is directed to minimal specific support for the statements at issue or detail about Dr. Caraballo's methodology.

In this specific context, I am without sufficient information at this time to draw the fine line between reliable and unreliable expert testimony on physical mesh properties based primarily on a doctor's clinical observations, or lack thereof. Accordingly, I **RESERVE** ruling until further testimony may be offered and evaluated firsthand at trial.

4. MSDS

Last, the plaintiffs argue Dr. Caraballo is unqualified to offer opinions on the MSDS issued by the polypropylene resin manufacturer. The plaintiffs do not challenge the reliability of Dr. Caraballo's opinions, but merely argue that because she believes Dr. Caraballo is unqualified to opine as to the general properties of polypropylene, Dr. Caraballo must likewise be unqualified to offer MSDS opinions. As discussed above, I find that Dr. Caraballo is qualified to opine on certain properties of polypropylene, but I reserved ruling on the reliability of those opinions. I find that as an experienced treating physician, Dr. Caraballo is qualified to offer opinions regarding the extent to which the MSDS is used in medical practice. The plaintiffs' motion on this point is **DENIED**, and I make no finding as to the reliability of Dr. Caraballo's opinions on this matter.

The plaintiffs' Motion to Exclude the Opinions and Testimony of Ricardo Caraballo M.D. is **DENIED in part**, **GRANTED in part**, and **RESERVED in part**.

VI. Effect of *Daubert* Ruling

I emphasize that my rulings excluding expert opinions under Rule 702 and *Daubert* are dispositive of their potential admissibility in these cases, but my rulings not to exclude expert opinions are not dispositive of their admissibility at trial. In other words, to the extent that certain opinions might be cumulative or might confuse or mislead the jury, they may still be excluded under Rule 403 or some other evidentiary rule. I will take up these issues as they arise.

VII. Conclusion

For the reasons discussed above, my rulings on BSC's motions are as follows: Motion to Exclude the Testimony of Michael Thomas Margolis, M.D. [ECF No. 29] is **GRANTED**; Motion to Exclude the Opinions and Testimony of Thomas Barker, Ph.D. [ECF No. 34] is **GRANTED**; Motion to Exclude the Opinions and Testimony of Jimmy Mays, Ph.D. [ECF No. 41] is **GRANTED**; Motion to Exclude the Opinions and Testimony of Russell Dunn, Ph.D. [ECF No. 43] is **GRANTED**; Motion to Exclude the Opinions and Testimony of Scott Guelcher, Ph.D. [ECF No. 44] is **GRANTED**; Motion to Exclude the Opinions and Testimony of Richard Trepeta, M.D. [ECF No. 45] is **GRANTED in part** and **DENIED in part**; Motion to Strike and Exclude the Opinions and Testimony of Vladimir Iakovlev, M.D. [ECF No. 52] is **GRANTED**; Motion to Exclude the Opinions and Testimony of Jerry Blaivas, M.D. [ECF No. 36] is **GRANTED in part** and **DENIED in part**; and Motion to Exclude the Opinions and Testimony of Bruce Rosenzweig, M.D. [ECF No. 33] is **GRANTED in part** and **DENIED in part;** Motion to Exclude the Opinions and Testimony of Bruce

Rosenzweig, M.D. [ECF No. 42] is **DENIED**; and Motion to Exclude the Opinions and Testimony of Marvin Goldberg, Ph.D [ECF No. 40] is **DENIED as MOOT**.[5]

My rulings on the plaintiffs' motions are as follows: Motion to Exclude the Opinions and Testimony of Gary L. Winn, Ph.D. [ECF No. 35] is **RESERVED**; Motion to Exclude or Limit the Testimony of Christine Brauer, Ph.D. [ECF No. 39] is **GRANTED**; Motion to Exclude the Testimony and Opinions of Dr. Stephen Spiegelberg, Ph.D. [ECF No. 49] is **GRANTED in part** and **DENIED in part**; Motion to Exclude the Opinions and Testimony of Stephen F. Badylak, D.V.M., Ph.D., M.D. [ECF No. 51] is **DENIED**; Motion to Exclude the Opinions and Testimony of Brian A. Feagins, M.D. [ECF No. 37] is **DENIED in part**, **RESERVED in Part**, and **GRANTED in part**; and Motion to Exclude the Opinions and Testimony of Ricardo Caraballo, M.D. [ECF No. 38] is **DENIED in part**, **GRANTED in part**, and **RESERVED in part**.

The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: June 14, 2016

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

[5] BSC filed notice withdrawing its motion regarding Dr. Goldberg. [ECF No. 77].